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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,835	10/13/2005	Frank Schafer	PC/4-33172A	9447
1095	7590	06/21/2007		
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			EXAMINER NOLAN, JASON MICHAEL	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 06/21/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,835	Applicant(s) SCHAFER ET AL.	
	Examiner Jason M. Nolan, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7, 15 and 16 is/are allowed.
- 6) ☒ Claim(s) 8-14 and 17-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/06/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-25 are pending in the instant application; of which **Claims 1, 3, 4 & 8-14** are currently amended and **Claims 15-25** are new.

Information Disclosure Statement

Applicants' information disclosure statement (IDS), filed on 12/06/2005 has been considered. Please refer to Applicants' copy of the 1449 submitted herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-14 & 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Villhauer, E.B. (US Patent 6,166,063; 12/26/2000). Described in the patent is 1-[3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-(S)-pyrrolidine, (see Example 1 in Column 7 and Claims 1, 2 & 5). *NOTE:* Said claims are either provided in a product-by-process format and examined based on the merits of the product and/or are written to include a small amount of the undesired (R)-enantiomer and/or are written to include the impurity (haloalkylene)dialkylammonium halide.

With respect to the claims that include a small amount of the undesired (R)-enantiomer; Villhauer envisioned, column 7, lines 4-10, the invention to include either pure (S) enantiomer or a racemic form. However, Examiner realizes that the synthesis in the prior art and that of the instant application both begin with L-prolinamide, which is enantiomerically pure; so, it is unlikely that any (R)-isomer would be formed in the reaction and therefore in possession by Applicant. If the Applicant does possess the undesired (R)-enantiomer, it would have to be formed either from a) epimerization of the chiral center (2-position having the cyano group) or b) a small amount of R-prolinamide from the bottle bought from the commercial source, (see Villhauer *et al. J. Med. Chem.* **2003**, 46, 2774-89; specifically Table 1. compound 8k and the discussion of contamination included below table on the left hand side).

With respect to **Claims 8, 10, 11 & 17-19**: "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985); see MPEP 2113.

Claims 12, 13, 20, 24 & 25 are all based on **Claim 12**, which is a pharmaceutical composition comprising a 2-cyanopyrrolidine compound and further comprising at least 0.00001% by weight the impurity (haloalkylene)dialkylammonium halide: the dehydrating reagent in step (b) of Claim 1 and also in Claims 15 & 16. Such a

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compound would be considered substantially pure by one of skill in the art; and further, the additional component of the composition is an impurity; therefore, not an inventive contribution to what is known in the prior art.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention: the terms "preferably" and "especially" render the claims indefinite because it is unclear whether the limitations following the phrase are part of the invention. See MPEP § 2173.05(d).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-14 & 21-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **Claims 1-9** of U.S. Patent No. **6,166,063** (Assignee: Novartis AG). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to overlapping subject matter. The compositions of the current application are not patentably distinct from those of the **'063** Patent, as described in the anticipation rejection above.

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Therefore an infringement on a Patent issued on the currently pending claims would also infringe on the '063 Patent.

Allowable Subject Matter

Claims 1-7, 15 & 16 describe a process for synthesizing 2-cyanopyrrolindines without isolation between each step, an invention that is free of the prior art.

Telephone Inquiry


Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is **Jason.Nolan@uspto.gov**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M^cKane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jason M. Nolan, Ph.D.
Examiner
Art Unit 1626



REBECCA ANDERSON
PATENT EXAMINER



Joseph K. M^cKane
Supervisory Patent Examiner
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Date: June 14, 2007